

## Work Instruction

REV.: C  
PAGE: 1 OF 27**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING PROCEDURE****SPECIFICATION NUMBER: TSS-0522**

---

### REVISION HISTORY

Revision	ECO Number	ECO Release Date	Initiator
A	0013074	02/21/2006	J. Amlen
B	0013710	08/09/06	J. Breazeale
C	0015485	09/12/07	J. Breazeale

### 1.0 PURPOSE

This testing procedure is intended to ensure proper installation and service so that the device will perform as intended. The person installing and servicing the device shall ensure that these tests and possible adjustments are documented as appropriate. All devices require periodic service and preventive maintenance. BWI has established and maintained schedules for the adjustment, cleaning and other maintenance of the Stockert Generator devices to ensure that manufacturing specifications are maintained. Maintenance activities, including the date and individual(s) performing the maintenance activities are documented according to 21 CFR 820.70(g)(1). BWI shall distribute the instructions and procedures where appropriate.

### 2.0 SCOPE

This procedure is applicable to the BWI US Technical Services Group.

### 3.0 REFERENCES

Reference No.	Reference Title
FORM451	Stockert Test Report.
M-5463-01	Stockert 70 RF Generator Kit
SOP-TSS-0507	Preventive Maintenance & Calibration
TSS-0520	Stockert Generator Calibration Procedure
M-5276-205	User Manual STOCKERT 70 Radiofrequency Generator
NA	Stockert Test Kit IFU (Provided with M-5463-48)

## Work Instruction

REV.: C  
PAGE: 2 OF 27

**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING PROCEDURE**

**SPECIFICATION NUMBER: TSS-0522**

### 4.0 MATERIALS AND EQUIPMENT (all equipment to have current calibration)

EQUIPMENT/MATERIAL	SPECIFICATION	SOURCE
Oscilloscope	Ability to measure RMS volts	TEK or user discretion
Safety analyzer	170B or equiv.	Biotek or user discretion
Load resistor	100 ohm 2% – 100 watt min.	Bird or user discretion
Water bath	STM0001 100 ohm mixture	In-house
Electrode	Brass plate	In-house
Extension cable	D-1170-10	Biosense Webster
Thermocouple catheter	D-1196	Biosense Webster
Thermistor catheter	D-1140	Biosense Webster
Stockert Test Kit	M-5463-48	Biosense Webster
32 Pole Extension Board	M-5463-46	Biosense Webster

**Table 1. Test materials and equipment.**

### 5.0 RESPONSIBILITIES

Function	Process Owner	Responsibility
Technical Services	Director of Technical Service	Ensures compliance.
Technical Services	Technical Services Representative	Perform Stockert Generator testing according to this work instruction.

### 6.0 TEST PROCEDURE

#### *System Setup*

- 6.1 Obtain FORM451.
- 6.2 Set up the heated water bath as follows:
  - 6.2.1 Turn on Thermometer
  - 6.2.2 Turn on circulating pump.
  - 6.2.3 Set temperature on pump controller to 37° C.
  - 6.2.4 Allow water to heat up until the thermometer temperature reading is 37° C - +/- 3°.
- 6.3 Turn on the Oscilloscope.
  - 6.3.1 If required set up oscilloscope to read RMS voltage.

#### *System interconnection.*

## Work Instruction

REV.: C  
PAGE: 3 OF 27**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING  
PROCEDURE****SPECIFICATION NUMBER: TSS-0522**

---

### Note

Please refer to illustrations **1** in this procedure for additional information. Please refer to Operator's manual if information is not included in this procedure.

- 6.3.2 Set up generator on workstation.
- 6.3.3 Connect Power cable to back of generator, and plug into the Bio-Safety Analyzer.
- 6.3.4 Connect Catheter cable to generator Catheter connector.
- 6.3.5 Connect TC Catheter to other end of the cable.
- 6.3.6 Connect blue indifferent cable from the 100-ohm non-inductive load resistors to the generator.
- 6.3.7 Attach the Tip of the catheter to the 100-ohm non-inductive load.
- 6.3.8 Connect the Footswitch to the generator.
- 6.3.9 Connect the Global port to the Generator as follows:
  - 6.3.9.1 Set up global port on workstation.
  - 6.3.9.2 Connect Power cable to Global port & plug into the wall power.
  - 6.3.9.3 Connect Communication cable between the Generator and to the EP-Stockert connector of Global port.
  - 6.3.9.4 Connect serial cable from Global port to PC.
  - 6.3.9.5 Turn on the Global Port.
- 6.3.10 Turn on the Generator.
  - 6.3.10.1 Verify the generator starts up correctly and all displays are correct as shown below.
    - 6.3.10.1.1 System should complete self test & Generator display should be as follows:
      - 6.3.10.1.1.1 Impedance = 90 - 110 ohms.
      - 6.3.10.1.1.2 Time = 60 seconds
      - 6.3.10.1.1.3 Temp (Room Temp) = 20degrees
      - 6.3.10.1.1.4 Set Temp display = 65 degrees
      - 6.3.10.1.1.5 Set Power display = 30 watts

## Work Instruction

REV.: C  
PAGE: 4 OF 27

**SPECIFICATION TITLE:** STOCKERT GENERATOR (ABLATION) TESTING  
**PROCEDURE**  
**SPECIFICATION NUMBER:** TSS-0522

---

### NOTE

If generator does not start-up correctly, correct problem before continuing with this procedure. Refer to Stockert Service Manual for troubleshooting information.

#### *System test*

- 6.4 Record the following information on the FORM451.
- 6.4.1 Customer name. Use the following names as indicated below.
- |         |                     |  |
|---------|---------------------|--|
| 6.4.1.1 | Inventory           | if the unit is to be put into inventory after testing. |
| 6.4.1.2 | Clinical department | if the unit belongs to the clinical group.             |
| 6.4.1.3 | Demo pool           | if the unit belongs to the demo/loaner pool.           |
| 6.4.1.4 | Individual TM       | if unit is returned from the sales group.              |
| 6.4.1.5 | Customers name      | if unit was returned from a customer.                  |
- 6.4.2 Model number (Located on front of generator)
- 6.4.3 Serial number (Located on rear of generator)
- 6.4.4 Date test to be performed
- 6.4.5 Name of person performing test.
- 6.4.6 Reason the test is being performed.

#### **6.5 Software Verification tests.**

- 6.5.1 Press "Menu" key to enter menu program.
- 6.5.2 Turn the selector knob to the "Identification menu".
- 6.5.3 Press "Start" key.
- 6.5.4 Turn the selector knob until the SN line appears.
- 6.5.5 **Record SN on FORM451.**

### NOTE

SN on back of unit must match SN in software test.

***Reject system if numbers do not match.***

- 6.5.6 Turn the selector knob until the Software version line appears.
- 6.5.7 Display will show "Version XXX.XXX."

## Work Instruction

REV.: C  
PAGE: 5 OF 27**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING  
PROCEDURE****SPECIFICATION NUMBER: TSS-0522**

---

- 6.5.8 Verify against latest revision of M-5463-01 (Stockert 70 RF Generator Kit) document.
- 6.5.9 **Record version on FORM451**
- 6.5.10 Continue turning the knob until “Software V test” is displayed.
- 6.5.11 Press “Start” key.
- 6.5.12 CPU 0 will be displayed in window.
  - 6.5.12.1 Compare the display in the Impedance, Time & Temperature windows with information listed on the FORM451. **Check box on FORM451 to verify display is correct.**
- 6.5.13 Turn selector knob until CPU 1 is displayed in window.
  - 6.5.13.1 Compare the display in the Impedance, Time & Temperature windows with information listed on FORM451.
  - 6.5.13.2 **Check box on FORM451 to verify display is correct.**
- 6.5.14 Turn selector knob until CPU Impedance is displayed in window.
  - 6.5.14.1 Compare the display in the Impedance, Time & Temperature displays with information listed on FORM451.
  - 6.5.14.2 **Check box on FORM451 to verify display is correct.**
- 6.5.15 Turn selector knob until CPU ECG 1 & 2 is displayed in window.
  - 6.5.15.1 Compare the display in the Impedance, Time & Temperature displays with the information listed on FORM451. **Check box on FORM451 to verify display is correct.**
- 6.5.16 Turn selector knob until CPU Multi-temp is displayed in window.
  - 6.5.16.1 Compare the display in the Impedance, Time & Temperature displays with the information listed on FORM451 sheet.
  - 6.5.16.2 **Check box on FORM451 to verify display is correct.**
- 6.5.17 Turn selector knob until CPU Option 5 is displayed in window.
  - 6.5.17.1 Compare the display in the Impedance, Time & Temperature displays with the information listed on FORM451. **Check box on FORM451 to verify display is correct.**
- 6.5.18 Turn selector knob until CPU Display is displayed in window.
  - 6.5.18.1 Compare the display in the Impedance, Time & Temperature displays with the information listed on FORM451. **Check box on FORM451 to verify display is correct.**

## Work Instruction

REV.: C  
PAGE: 6 OF 27

**SPECIFICATION TITLE:** STOCKERT GENERATOR (ABLATION) TESTING  
PROCEDURE

**SPECIFICATION NUMBER:** TSS-0522

---

6.5.19 Turn selector knob until CPU Documentation is displayed in window.

6.5.19.1 Compare the display in the Impedance, Time & Temperature displays with the information listed on FORM451. **Check box on FORM451 to verify display is correct.**

6.5.20 Press “STOP” key to exit test.

### 6.6 Maximum Displayed output test.

6.6.1 Check the maximum wattage output as follows:

6.6.1.1 Press “F2” key.

6.6.1.2 Turn the selector knob clockwise until maximum value is displayed.

#### NOTE

Maximum available output must not exceed 50 watts or 70 watts as appropriate.

***Recalibrate system if displayed output exceeds 50 watts or 70 watts as appropriate.***

6.6.2 **Check box on FORM451 to verify display is correct.**

### 6.7 Catheter selection menu verification.

6.7.1 Press and hold the “Catheter” key until “Select catheter” appears.

6.7.2 Scroll through the catheter selections by turning the selector knob clockwise.

6.7.3 The following choices should appear as you rotate the knob:

6.7.3.1 Biosense Webster.

6.7.3.2 B/Webster Fast

6.7.3.3 Dual Sensor 8mm

6.7.3.4 ThermoCool

6.7.3.5 manual unipolar.

6.7.4 **Check box on FORM451 to verify display is correct.**

6.7.5 Press “STOP” key to exit test.

### 6.8 EPWin Setup

6.8.1 Turn on Laptop.

6.8.2 From Desktop screen select EPWin and double click on icon to launch program.

## Work Instruction

REV.: C  
PAGE: 7 OF 27**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING  
PROCEDURE****SPECIFICATION NUMBER: TSS-0522**

---

- 6.8.3 Wait for program to start up and main menu is displayed.
- 6.8.4 Insure communication is established between Generator & PC by insuring that yellow bar is active.
- 6.8.5 Select "Patient".
- 6.8.6 Select "New Patient ID".
- 6.8.7 In "ID window" enter SN of generator to be tested. (Example ST-XXXX)
- 6.8.8 Select OK to advance to next screen.
- 6.8.9 In the box labeled "First name" enter "Stockert 70" and press "Enter" key.
- 6.8.10 In the box labeled "Surname" enter "ST-XXXX" (XXXX= SN of system), and press "Enter" key.
- 6.8.11 In the box labeled date of birth enter "Today's date", and press "Enter" key
- 6.8.12 Select OK to advance to next screen.
- 6.8.13 In the box labeled "Operator" enter "Name of person doing test"
- 6.8.14 Select "Close" to advance to next screen.
- 6.8.15 You should now return to the main screen.

### Note

Please refer to illustration **2** included in this procedure for location of controls & displays.

## **6.9 Generator Functional test (For 50W)**

- 6.9.1 Press the "Standard mode" key on generator.
- 6.9.2 Press F2 key.
- 6.9.3 Turn selector knob until generator displays 50 watts.
- 6.9.4 Depress the "Footswitch".
- 6.9.5 The RF power should come on and be delivered to tip of catheter.
  - 6.9.5.1 On generator the RF indicator lamp will illuminate and an audible sound will be heard.
  - 6.9.5.2 A sine wave representing the RF output will be displayed on the Oscilloscope screen.
  - 6.9.5.3 Locate the RMS voltage displayed on bottom of oscilloscope screen.
  - 6.9.5.4 **Record the actual value from scope on FORM451.**
- 6.9.6 Release footswitch to end test.

## Work Instruction

REV.: C  
PAGE: 8 OF 27**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING  
PROCEDURE****SPECIFICATION NUMBER: TSS-0522**

---

### NOTE

RMS Voltage must be range between 67 to 74 VRMS. If the voltage is not within tolerance calibrate Power output of generator per 7.0 of TSS-0520.

#### Voltage Display Verification

6.9.7 Verify and document the Voltage display of the Generator and PC as follows:

- 6.9.7.1 Press "Menu" key.
- 6.9.7.2 Turn selector knob until "Display menu" appears in window.
- 6.9.7.3 Press "START" key to enter submenu.
- 6.9.7.4 Turn selector knob until "Voltage & Power" is displayed in window.
- 6.9.7.5 Press "F1" key.
- 6.9.7.6 Press "STOP" key to exit.
- 6.9.7.7 Turn selector knob until generator displays 50 watts.
- 6.9.7.8 Press the Footswitch.
  - 6.9.7.8.1 View voltage value displayed on Generator.
  - 6.9.7.8.2 **Record value on FORM451.**
  - 6.9.7.8.3 View voltage value on PC display.
  - 6.9.7.8.4 **Record value on FORM451.**
- 6.9.7.9 Release the footswitch to end test.

### NOTE

Voltage must range between 67 to 74 VRMS. If the voltage is not within tolerance calibrate voltage display of generator per 8.0 of TSS-0520.

#### Current Display Verification

6.9.8 Verify and document the Current display of the Generator and PC as follows:

- 6.9.8.1 Press "Menu" key.
- 6.9.8.2 "Voltage & Power" will appear in display window.
- 6.9.8.3 Turn selector knob until "Current & Power" is displayed in window.
- 6.9.8.4 Press "F1" key.
- 6.9.8.5 Press "STOP" key to exit.



## Work Instruction

REV.: C  
PAGE: 9 OF 27**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING PROCEDURE****SPECIFICATION NUMBER: TSS-0522**

---

- 6.9.8.6 Turn selector knob until generator displays 50 watts.
- 6.9.8.7 Press the Footswitch.
  - 6.9.8.7.1 View Current value displayed on Generator.
  - 6.9.8.7.2 **Record value on FORM451.**
  - 6.9.8.7.3 View Current value on PC display.
  - 6.9.8.7.4 **Record value on FORM451.**
- 6.9.8.8 Release the footswitch to end test.

### NOTE

Current value must range between 710 to 730 milli-amps (mA). If the current is not within tolerance calibrate display of generator per 9.0 of TSS-0520.

### Impedance Display Verification

- 6.9.9 Verify and document the Impedance display of the Generator and PC as follows:
  - 6.9.9.1 Press F2 key.
  - 6.9.9.2 Turn selector knob until generator displays 50 watts.
  - 6.9.9.3 Press the "START" key.
    - 6.9.9.3.1 View Impedance value displayed on Generator.
    - 6.9.9.3.2 **Record value on FORM451.**
    - 6.9.9.3.3 View Impedance value on PC display.
    - 6.9.9.3.4 **Record value on FORM451.**
  - 6.9.9.4 Press "STOP" key to exit test.

### NOTE

Impedance must range between 90 to 110 ohms. If the impedance is not within tolerance calibrate display of generator per 10.0 of TSS-0520.

## 6.10 Mode display Verification.

### 6.10.1 Standard mode Display Verification

- 6.10.1.1 Press the "Standard mode" key on generator.
- 6.10.1.2 Press F2 key.
- 6.10.1.3 Turn selector knob until generator displays 50 watts.
- 6.10.1.4 Press the Footswitch.

## Work Instruction

REV.: C  
PAGE: 10 OF 27**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING PROCEDURE****SPECIFICATION NUMBER: TSS-0522**

---

6.10.1.5 The RF power should come on and be delivered to tip of catheter.

6.10.1.5.1 On generator the RF indicator lamp will illuminate and an audible sound will be heard.

6.10.1.5.2 A sine wave representing the RF output will be displayed on the Oscilloscope screen.

6.10.1.5.3 Locate the RMS voltage shown on bottom of oscilloscope screen.

6.10.1.5.4 **Record the highest displayed scope value on the FORM451.**

6.10.1.5.5 **Record the actual max Power displayed on generator on FORM451.**

6.10.1.5.6 **Record the actual max Power on PC display on FORM451.**

6.10.1.6 Release the footswitch to end test.

### 6.10.2 Manual mode Display Verification

6.10.2.1 Press the "Manual mode" key on generator.

6.10.2.1.1 Turn selector knob until generator displays 50 watts.

6.10.2.1.2 Press the "START" key.

6.10.2.1.3 The RF power should come on and be delivered to tip of catheter.

6.10.2.1.3.1 On generator the RF indicator lamp will illuminate and an audible sound will be heard.

6.10.2.1.3.2 A sine wave representing the RF output will be displayed on the Oscilloscope screen.

6.10.2.1.3.3 Locate the RMS voltage shown on bottom of oscilloscope screen.

6.10.2.1.3.4 **Record the highest displayed scope value on FORM451.**

6.10.2.1.3.5 **Record the actual max Power output on Generator on FORM451.**

6.10.2.1.3.6 **Record the actual max Power output on PC display on FORM451.**

## Work Instruction

REV.: C  
PAGE: 11 OF 27**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING  
PROCEDURE****SPECIFICATION NUMBER: TSS-0522**

---

6.10.2.1.4 Press "STOP" key to end test.

### 6.11 Temperature Verification

6.11.1 TC Catheter temperature verification.

- 6.11.1.1 Press the "Standard mode" key on generator.
- 6.11.1.2 Press F2 key.
- 6.11.1.3 Turn selector knob until generator displays 50 watts.
- 6.11.1.4 Place the thermocouple catheter into the Water bath.
- 6.11.1.5 Submerge the tip into the water bath.
- 6.11.1.6 Insure Impedance on generator is between 90 to 110 ohms.
- 6.11.1.7 Press "START" key for 1 second.
- 6.11.1.8 Press "STOP" key to end test.
- 6.11.1.9 **Record the Actual thermometer reading on FORM451.**
- 6.11.1.10 **Record Actual TC temperature displayed on generator on FORM451.**
- 6.11.1.11 **Record actual TC temperature displayed on Laptop on FORM451.**

#### NOTE

Temperature must range between 34 to 40 degrees. If the temperature is not within tolerance calibrate display of generator per 11.0 of TSS-0520.

- 6.11.1.12 Press the "Standard mode" key on generator.
- 6.11.1.13 Press F2 key.
- 6.11.1.14 Turn selector knob until generator displays 50 watts.
- 6.11.1.15 Press F1 key.
- 6.11.1.16 Turn Selector knob until set temperature limit reaches 70 degrees.
- 6.11.1.17 Turn off the circulator pump.
- 6.11.1.18 Place catheter tip close to the surface of the Water bath.
- 6.11.1.19 Press the "START" key.
- 6.11.1.20 Allow the generator to heat the tip of the catheter to the set point temperature (70).
- 6.11.1.21 **Record Actual TC temperature displayed on generator on FORM451.**

## Work Instruction

REV.: C  
PAGE: 12 OF 27**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING PROCEDURE****SPECIFICATION NUMBER: TSS-0522**

---

6.11.1.22 **Record actual TC temperature displayed on Laptop on FORM451.**

6.11.1.23 Press "STOP" key to end test.

### NOTE

Temperature range must be between 68 to 72 degrees. If the temperature is not within tolerance calibrate display of generator per 11.0 of TSS-0520.

### 6.11.2 THR Catheter temperature verification.

6.11.2.1 Replace the TC catheter with the THR catheter.

6.11.2.2 Press the "Standard mode" key on generator.

6.11.2.3 Press F2 key.

6.11.2.4 Turn selector knob until generator displays 50 watts.

6.11.2.5 Place the Thermistor catheter into the Water bath.

6.11.2.6 Turn on the circulating pump.

6.11.2.7 Submerge the tip of the catheter into the water bath.

6.11.2.8 Insure Impedance on generator is between 90 to 110 ohms.

6.11.2.9 Press "START" key for 1 second.

6.11.2.10 Press "STOP" key to end test.

6.11.2.11 **Record the Actual thermometer reading on FORM451.**

6.11.2.12 **Record Actual TC temperature displayed on generator on FORM451.**

6.11.2.13 **Record actual TC temperature displayed on Laptop on FORM451.**

### NOTE

Temperature range must be between 34 to 40 degrees. If the temperature is not within tolerance calibrate display of generator per 11.0 of TSS-0520.

6.11.2.14 Place catheter tip close to the surface of the Water bath.

6.11.2.15 Turn off the circulator.

6.11.2.16 Press the "Standard mode" key on generator.

6.11.2.17 Press F2 key.

6.11.2.18 Turn selector knob until generator displays 50 watts.

6.11.2.19 Press F1 key.

## Work Instruction

REV.: C  
PAGE: 13 OF 27**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING PROCEDURE****SPECIFICATION NUMBER: TSS-0522**

---

- 6.11.2.20 Turn Selector knob until set temperature limit reaches 70 degrees.
- 6.11.2.21 Press the "START" key.
- 6.11.2.22 Allow the generator to heat the tip of the catheter to the set point temperature (70).
- 6.11.2.23 **Record actual THR temperature displayed on generator on FORM451.**
- 6.11.2.24 **Record actual THR temperature displayed on Laptop on FORM451.**
- 6.11.2.25 Press "STOP" key to end test.

### NOTE

Temperature range must be between 68 to 72 degrees. If the temperature is not within tolerance calibrate display of generator per 11.0 of TSS-0520.

- 6.11.2.26 Disconnect THR catheter and reconnect TC catheter.

## 6.12 Footswitch test

6.12.1 Verify footswitch operation as follows:

- 6.12.1.1 Press "Menu" key.
- 6.12.1.2 Press "Menu" key again.
- 6.12.1.3 Turn selector knob until "Test menu" appears in window.
- 6.12.1.4 Press "START" key to enter submenu.
- 6.12.1.5 "Test Footpedal" will appear in display window
- 6.12.1.6 Press "START" key.
- 6.12.1.7 Depress footswitch.
  - 6.12.1.7.1 Display in window should be "Footswitch on".
- 6.12.1.8 Release footswitch and insure display indicates correctly.
  - 6.12.1.8.1 Display in window should be "Footswitch off".
- 6.12.1.9 Unplug footswitch and insure display indicate correctly.
  - 6.12.1.9.1 Display in Window should be "No Footswitch".
- 6.12.1.10 Check box on data sheet to conform test passed.
- 6.12.1.11 Press "STOP" key to end test.

**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING  
PROCEDURE****SPECIFICATION NUMBER: TSS-0522**

---

**6.13 EPWin/Generator Display Verification.**

6.13.1 Press the "Standard mode" key on generator.

6.13.2 Press F2 key.

6.13.3 Turn selector knob until generator displays 50 watts.

6.13.4 Press the "START" key.

6.13.4.1 **Record the actual max Power value displayed on  
Generator on FORM451.**6.13.4.2 **Record the actual max Impedance value displayed on  
Generator on FORM451.**6.13.4.3 **Record the actual max Temperature value displayed on  
Generator on FORM451.**6.13.4.4 **Record the actual max Power value displayed on PC on  
FORM451.**6.13.4.5 **Record the actual max Impedance value displayed on PC  
on FORM451.**6.13.4.6 **Record the actual max Temperature value displayed on  
PC on FORM451.**

6.13.5 Press the "STOP" key to end test.

6.13.6 Close &amp; save test record on PC as follows:

6.13.6.1 From EPWin main screen Select Patient.

6.13.6.2 Select Save Patient Data, press "enter" key.

6.13.6.3 Select Save; press "Enter" key.

6.13.6.4 Wait until data is finished saving and pointer return to arrow.

6.13.6.5 Select "Cancel" to return to Patient menu.

6.13.6.6 Select "OK" to return to main screen.

**6.14 Safety Test.**

6.14.1 Connect the safety analyzer test lead to the ground stud located on the rear of the generator.

6.14.2 Turn on the analyzer.

6.14.3 Set the analyzer for ground lead resistance.

6.14.3.1 Press the "Standard mode" key on generator.

6.14.3.2 Press F2 key.

## Work Instruction

REV.: C  
PAGE: 15 OF 27**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING PROCEDURE****SPECIFICATION NUMBER: TSS-0522**

---

6.14.3.3 Turn selector knob until generator displays 50 watts.

6.14.3.4 Press the "START" key on generator.

6.14.3.5 Record value displayed on analyzer on FORM451.

6.14.3.6 Lead resistance value must less than  $0.2\Omega$

6.14.3.7 Press the "STOP" key to end test.

6.14.4 Set the safety analyzer for chassis leakage current.

6.14.4.1 Press the "START" key on generator.

6.14.4.2 Record value displayed on analyzer on FORM451.

6.14.4.3 Leakage current value must less than  $500\mu A$

6.14.4.4 Press the "STOP" key to end test.

### **6.15 Test completion.**

6.15.1 Disconnect generator & return all parts to the shipping container.

6.15.2 Verify all parts are returned to shipping container by using checklist.

6.15.3 Forward completed Form451 (Stockert Test Report) and certificate of conformance to QA for review and signature. QA will return the original report to TSS upon completion.

6.15.4 Make copies of test report and shipping report and include the copy in the manual bag.

6.15.5 Add installation report to Manual bag.

6.15.6 Close case and put a "Completed" sticker on front of case.

6.15.7 Transfer the unit to the appropriate customer or Stock location.

### **7.0 Generator Functional test (For 70W)**

7.1 Press the "Standard mode" key on generator

7.2 Press F2 key.

7.3 Turn selector knob until generator displays 70 watts.

7.4 Depress the "Footswitch".

7.5 The RF power should come on and be delivered to tip of catheter.

7.5.1 On generator the RF indicator lamp will illuminate and an audible sound will be heard.

7.5.2 A sine wave representing the RF output will be displayed on the Oscilloscope screen.

**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING PROCEDURE**

**SPECIFICATION NUMBER: TSS-0522**

---

7.5.3 Locate the RMS voltage displayed on bottom of oscilloscope screen.

7.5.4 **Record the actual value from scope on FORM451.**

7.6 Release footswitch to end test.

#### NOTE

RMS Voltage must be range between 79 to 88 VRMS. If the voltage is not within tolerance calibrate Power output of generator per 7.0 of TSS-0520.

### 7.7 Voltage Display Verification

7.7.1 Verify and document the Voltage display of the Generator and PC as follows:

7.7.1.1 Press "Menu" key.

7.7.1.2 Turn selector knob until "Display menu" appears in window.

7.7.1.3 Press "START" key to enter submenu.

7.7.1.4 Turn selector knob until "Voltage & Power" is displayed in window.

7.7.1.5 Press "F1" key.

7.7.1.6 Press "STOP" key to exit.

7.7.1.7 Turn selector knob until generator displays 70 watts.

7.7.1.8 Press the Footswitch.

7.7.1.8.1 View voltage value displayed on Generator.

7.7.1.8.2 **Record value on FORM451.**

7.7.1.8.3 View voltage value on PC display.

7.7.1.8.4 **Record value on FORM451.**

7.7.1.9 Release the footswitch to end test.

#### NOTE

Voltage must range between 79 to 88VRMS. If the voltage is not within tolerance calibrate voltage display of generator per 8.0 of TSS-0520.

### 7.8 Current Display Verification

7.8.1 Verify and document the Current display of the Generator and PC as follows:

7.8.1.1 Press "Menu" key.

7.8.1.2 "Voltage & Power" will appear in display window.



## Work Instruction

REV.: C  
PAGE: 17 OF 27**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING PROCEDURE****SPECIFICATION NUMBER: TSS-0522**

---

7.8.1.3 Turn selector knob until "Current & Power" is displayed in window.

7.8.1.4 Press "F1" key.

7.8.1.5 Press "STOP" key to exit.

7.8.1.6 Turn selector knob until generator displays 70 watts.

7.8.1.7 Press the Footswitch.

7.8.7.1 View Current value displayed on Generator.

**7.8.7.2 Record value on FORM451.**

7.8.7.3 View Current value on PC display.

**7.8.7.4 Record value on FORM451.**

7.8.1.8 Release the footswitch to end test.

### NOTE

Current value must range between 800 to 880 milli-amps. If the current is not within tolerance calibrate display of generator per 9.0 of TSS-0520.

## 7.9 Impedance Display Verification

7.9.1 Verify and document the Impedance display of the Generator and PC as follows:

7.9.1.1 Press F2 key.

7.9.1.2 Turn selector knob until generator displays 70 watts.

7.9.1.3 Press the "START" key.

7.9.1.3.1 View Impedance value displayed on Generator.

**7.9.1.3.2 Record value on FORM451.**

7.9.1.3.3 View Impedance value on PC display.

**7.9.1.3.4 Record value on FORM451.**

7.9.1.4 Press "STOP" key to exit test.

### NOTE

Impedance must range between 90 to 110 ohms. If the impedance is not within tolerance calibrate display of generator per 10.0 of TSS-0520.

## 7.10 Mode display Verification.

### 7.10.1 Standard mode Display Verification

7.10.1.1 Press the "Standard mode" key on generator.

## Work Instruction

REV.: C  
PAGE: 18 OF 27**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING PROCEDURE****SPECIFICATION NUMBER: TSS-0522**

---

- 7.10.1.2 Press F2 key.
- 7.10.1.3 Turn selector knob until generator displays 70 watts.
- 7.10.1.4 Press the Footswitch.
- 7.10.1.5 The RF power should come on and be delivered to tip of catheter.
  - 7.10.1.5.1 On generator the RF indicator lamp will illuminate and an audible sound will be heard.
  - 7.10.1.5.2 A sine wave representing the RF output will be displayed on the Oscilloscope screen.
  - 7.10.1.5.3 Locate the RMS voltage shown on bottom of oscilloscope screen.
  - 7.10.1.5.4 **Record the highest displayed scope value on FORM451.**
  - 7.10.1.5.5 **Record the actual max Power displayed on generator on FORM451.**
  - 7.10.1.5.6 **Record the actual max Power on PC display on FORM451.**
- 7.10.1.6 Release the footswitch to end test.

### 7.11 Manual mode Display Verification

- 7.11.1 Press the "Manual mode" key on generator.
  - 7.11.1.1 Turn selector knob until generator displays 70 watts.
  - 7.11.1.2 Press the "START" key.
  - 7.11.1.3 The RF power should come on and be delivered to tip of catheter.
    - 7.11.1.3.1 On generator the RF indicator lamp will illuminate and an audible sound will be heard.
    - 7.11.1.3.2 A sine wave representing the RF output will be displayed on the Oscilloscope screen.
    - 7.11.1.3.3 Locate the RMS voltage shown on bottom of oscilloscope screen.
    - 7.11.1.3.4 **Record the highest displayed scope value on FORM451.**
    - 7.11.1.3.5 **Record the actual max Power output on Generator on FORM451.**

## Work Instruction

REV.: C  
PAGE: 19 OF 27

**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING PROCEDURE**  
**SPECIFICATION NUMBER: TSS-0522**

---

### 7.11.1.3.6 Record the actual max Power output on PC display on FORM451.

7.11.1.4 Press "STOP" key to end test.

## 7.12 Temperature Verification

### 7.12.1 TC Catheter temperature verification.

7.12.1.1 Press the "Standard mode" key on generator.

7.12.1.2 Press F2 key.

7.12.1.3 Turn selector knob until generator displays 70 watts.

7.12.1.4 Place the thermocouple catheter into the Water bath.

7.12.1.5 Submerge the tip into the water bath.

7.12.1.6 Insure Impedance on generator is between 90 to 110 ohms.

7.12.1.7 Press "START" key for 1 second.

7.12.1.8 Press "STOP" key to end test.

7.12.1.9 **Record the Actual thermometer reading on FORM451.**

7.12.1.10 **Record Actual TC temperature displayed on generator on FORM451.**

7.12.1.11 **Record actual TC temperature displayed on Laptop on FORM451.**

### NOTE

Temperature must range between 34 to 40 degrees. If the temperature is not within tolerance calibrate display of generator per 11.0 of TSS-0520.

7.12.1.12 Press the "Standard mode" key on generator.

7.12.1.13 Press F2 key.

7.12.1.14 Turn selector knob until generator displays 70 watts.

7.12.1.15 Press F1 key.

7.12.1.16 Turn Selector knob until set temperature limit reaches 70 degrees.

7.12.1.17 Turn off the circulator pump.

7.12.1.18 Place catheter tip close to the surface of the Water bath.

7.12.1.19 Press the "START" key.

7.12.1.20 Allow the generator to heat the tip of the catheter to the set point temperature (70).

## Work Instruction

REV.: C  
PAGE: 20 OF 27**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING PROCEDURE****SPECIFICATION NUMBER: TSS-0522**

---

7.12.1.21 **Record Actual TC temperature displayed on generator on FORM451.**

7.12.1.22 **Record actual TC temperature displayed on Laptop on FORM451.**

7.12.1.23 Press "STOP" key to end test.

### NOTE

Temperature range must be between 68 to 72 degrees. If the temperature is not within tolerance calibrate display of generator per 11.0 of TSS-0520.

### 7.13 **THR Catheter temperature verification.**

7.13.1 Replace the TC catheter with the THR catheter.

7.13.2 Press the "Standard mode" key on generator.

7.13.3 Press F2 key.

7.13.4 Turn selector knob until generator displays 70 watts.

7.13.5 Place the Thermistor catheter into the Water bath.

7.13.6 Turn on the circulating pump.

7.13.7 Submerge the tip of the catheter into the water bath.

7.13.8 Insure Impedance on generator is between 90 to 110 ohms.

7.13.9 Press "START" key for 1 second.

7.13.10 Press "STOP" key to end test.

7.13.11 **Record the Actual thermometer reading on FORM451.**

7.13.12 **Record Actual TC temperature displayed on generator on FORM451.**

7.13.13 **Record actual TC temperature displayed on Laptop on FORM451.**

### NOTE

Temperature range must be between 34 to 40 degrees. If the temperature is not within tolerance calibrate display of generator per 11.0 of TSS-0520.

7.13.14 Place catheter tip close to the surface of the Water bath.

7.13.15 Turn off the circulator.

7.13.16 Press the "Standard mode" key on generator.

7.13.17 Press F2 key.

7.13.18 Turn selector knob until generator displays 70 watts.

## Work Instruction

REV.: C  
PAGE: 21 OF 27**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING PROCEDURE****SPECIFICATION NUMBER: TSS-0522**

---

7.13.19 Press F1 key.

7.13.20 Turn Selector knob until set temperature limit reaches 70 degrees.

7.13.21 Press the "START" key.

7.13.22 Allow the generator to heat the tip of the catheter to the set point temperature (70).

7.13.23 **Record actual THR temperature displayed on generator on FORM451.**

7.13.24 **Record actual THR temperature displayed on Laptop on FORM451.**

7.13.25 Press "STOP" key to end test.

### NOTE

Temperature range must be between 68 to 72 degrees. If the temperature is not within tolerance calibrate display of generator per 11.0 of TSS-0520.

7.13.26 Disconnect THR catheter and cable and connect 8mm DS catheter and cable.

7.14 8mm DS catheter temperature verification

7.14.1 Select Dual Sensor 8mm for catheter selection.

7.14.1.1 Refer to user manual for procedure.

7.14.2 Press "Menu" key

7.14.3 Turn selector knob until "Test Menu" appears in window.

7.14.4 Press "START" to enter submenu

7.14.5 Turn selector knob until "dual temp test" appears in window.

7.14.6 Press "START" key.

7.14.7 Place the 8mm DS catheter tip into water bath.

7.14.8 Turn on the circulating pump.

7.14.9 Insure impedance is between 90-110 ohms.

7.14.10 Insure water bath temp reads 37 degrees on digital thermometer.

7.14.11 Record the thermometer temperature reading on FOM451.

7.14.12 Record both "T1" and "T2" values displayed on generator onto FORM 451.

7.14.13 "T1" value is on left side of main display window. "T2" is on right side of main display window.

## Work Instruction

REV.: C  
PAGE: 22 OF 27

**SPECIFICATION TITLE:** **STOCKERT GENERATOR (ABLATION) TESTING PROCEDURE**  
**SPECIFICATION NUMBER:** **TSS-0522**

---

### NOTE

Temperature range must be between 34 to 40 degrees. If the temperature is not within tolerance calibrate display of generator per step 12.0 of TSS-0520.

7.14.14 Press the "STOP" key to exit the "dual temp test".

7.14.15 Press F1 key

7.14.16 Turn selector knob until set temperature limit reaches 70 degrees C.

7.14.17 Turn off the circulating pump.

7.14.18 Press the F2 key

7.14.19 Turn selector knob until generator displays 70 watts

7.14.20 Place catheter tip close to surface of water bath.

7.14.21 Press the "START" key

7.14.22 Allow the generator to heat the catheter tip to temperature set point.

7.14.23 Record actual DS temperature displayed on the generator on FORM451

7.14.24 Record actual DS temperature displayed on the laptop on FORM451.

7.14.25 Press "STOP" key to end test.

### NOTE

For 70 degree C testing only 1 temperature value will be displayed on both the generator and laptop and recorded on FORM451 in appropriate box.

## 7.15 Footswitch test

7.15.1 Verify footswitch operation as follows:

7.15.1.1 Press "Menu" key.

7.15.1.2 Press "Menu" key again.

7.15.1.3 Turn selector knob until "Test menu" appears in window.

7.15.1.4 Press "START" key to enter submenu.

7.15.1.5 "Test Footpedal" will appear in display window

7.15.1.6 Press "START" key.

7.15.1.7 Depress footswitch.

7.15.1.7.1 Display in window should be "Footswitch on".

7.15.1.8 Release footswitch and insure display indicates correctly.

7.15.1.8.1 Display in window should be "Footswitch off".

## Work Instruction

REV.: C  
PAGE: 23 OF 27**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING PROCEDURE****SPECIFICATION NUMBER: TSS-0522**

---

7.15.1.9 Unplug footswitch and insure display indicate correctly.

7.15.1.9.1 Display in Window should be "No Footswitch".

7.15.1.10 Check box on FORM451 to conform test passed.

7.15.1.11 Press "STOP" key to end test.

### 7.16 EP Cooler Functional Test

7.16.1 Set Stockert Generator to "Manual Mode".

7.16.2 Connect Stockert Generator to the Stockert Test Kit (See Stockert Test Kit IFU for detailed connection instructions).

7.16.3 Push start and slowly increase power.

7.16.4 Fans must turn on at 3.5W. (Tolerance (+/-) 1.5W)

7.16.5 If fans turn on as prescribed above check the "Pass" box for "Test 1" on FORM451

7.16.5.1 If the fans do not turn on check the "Fail" box for "Test 1" on FORM451.

7.16.5.1.1 Confirm proper installation of the EP Cooler upgrade.

7.16.5.1.2 Return to Step 6.0 (Retain all completed FORM451's)

7.16.6 Turn off Generator.

7.16.7 Disconnect the Stockert Test Kit.

7.16.8 Connect the 32-Pin Extension Board to the generator and attach to the NIS board.

7.16.9 Turn on the Generator.

7.16.10 Short the temperature sensor at the NIS board (See Illustration 1 for location). The temperature sensor can be shorted with any conductive and insulated material.

7.16.11 The fans must turn on when the temperature sensor is shorted.

7.16.12 If the fans turn on when temperature sensor is shorted check "Pass" for "Test 2".

7.16.12.1 If the fans do not turn on check the "Fail" box for "Test 2" on FORM451.

7.16.12.1.1 Confirm proper installation of the EP Cooler upgrade.

7.16.12.1.2 Return to Step 6.0 (Retain all completed FORM451's)

7.16.13 Disconnect the 32-Pin Extension Board and re-attach the NIS Board to the Stockert Generator.

**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING  
PROCEDURE****SPECIFICATION NUMBER: TSS-0522**

---

**7.17 EPWin/Generator Display Verification.**

- 7.17.1 Press the "Standard mode" key on generator.
- 7.17.2 Press F2 key.
- 7.17.3 Turn selector knob until generator displays 70 watts.
- 7.17.4 Press the "START" key.
  - 7.17.4.1 **Record the actual max Power value displayed on Generator.**
  - 7.17.4.2 **Record the actual max Impedance value displayed on Generator.**
  - 7.17.4.3 **Record the actual max Temperature value displayed on Generator.**
  - 7.17.4.4 **Record the actual max Power value displayed on PC.**
  - 7.17.4.5 **Record the actual max Impedance value displayed on PC.**
  - 7.17.4.6 **Record the actual max Temperature value displayed on PC.**
- 7.17.5 Press the "STOP" key to end test.
- 7.17.6 Close & save test record on PC as follows:
  - 7.17.6.1 From EPWin main screen Select Patient.
  - 7.17.6.2 Select Save Patient Data, press "enter" key.
  - 7.17.6.3 Select Save; press "Enter" key.
  - 7.17.6.4 Wait until data is finished saving and pointer return to arrow.
  - 7.17.6.5 Select "Cancel" to return to Patient menu.
  - 7.17.6.6 Select "OK" to return to main screen.

**7.18 Safety Test.**

- 7.18.1 Connect the safety analyzer test lead to the ground stud located on the rear of the generator.
- 7.18.2 Turn on the analyzer.
- 7.18.3 Set the analyzer for ground lead resistance.
  - 7.18.3.1 Press the "Standard mode" key on generator.
  - 7.18.3.2 Press F2 key.
  - 7.18.3.3 Turn selector knob until generator displays 70 watts.
  - 7.18.3.4 Press the "START" key on generator.



## Work Instruction

REV.: C  
PAGE: 25 OF 27**SPECIFICATION TITLE: STOCKERT GENERATOR (ABLATION) TESTING  
PROCEDURE****SPECIFICATION NUMBER: TSS-0522**

---

7.18.3.5 Record value displayed on analyzer on FORM451..

7.18.3.6 Lead resistance value must less than  $0.2\Omega$ 

7.18.3.7 Press the "STOP" key to end test.

7.18.4 Set the safety analyzer for chassis leakage current.

7.18.4.1 Press the "START" key on generator.

7.18.4.2 Record value displayed on analyzer on FORM451.

7.18.4.3 Leakage current value must be less than  $500\mu A$ 

7.18.4.4 Press the "STOP" key to end test.

**7.19 Final Stockert Generator Verification.**

7.19.1 Disconnect generator &amp; return all parts to the shipping container.

7.19.2 Verify all parts are returned to shipping container by using checklist.

7.19.3 Sign FORM451 "Performed by" and record "Date" test completed.

7.19.4 Obtain "Reviewed by" signature and date from a technician qualified to perform Stockert Generator testing or Technical Service, Manager/Director.

7.19.5 Make copies of test report and shipping report and include the copy in the manual bag.

7.19.6 Add installation report to Manual bag.

7.19.7 Close case and put a "Completed" sticker on front of case.

7.19.8 Transfer the unit to the appropriate customer or Stock location.

**8.0 RECORD RETENTION**

All documents produced as a result of procedural compliance are retained per the requirements documented in Record Retention Schedule.

**9.0 ATTACHMENTS**

Illustration #1, NIS Board Solder Test Points

Illustration #2, System Interconnection Schematic

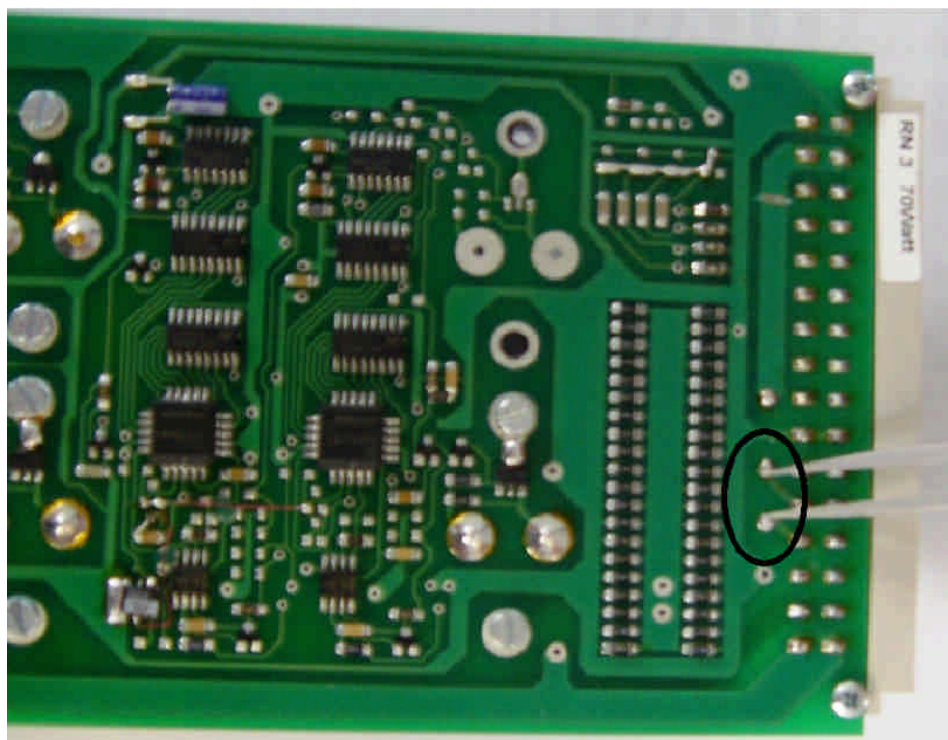
## Work Instruction

REV.: C  
PAGE: 26 OF 27

**SPECIFICATION TITLE:** STOCKERT GENERATOR (ABLATION) TESTING  
**PROCEDURE**  
**SPECIFICATION NUMBER:** TSS-0522

---

### ILLUSTRATION # 1



NIS board solder test points

**SPECIFICATION TITLE:**

**STOCKERT GENERATOR (ABLATION) TESTING  
PROCEDURE**

**SPECIFICATION NUMBER:**

**TSS-0522**

## ILLUSTRATION # 2

### SYSTEM INTERCONNECTION SCHEMATIC

